

REMARKS

The July 22, 2009 Official Action has been carefully considered. In view of the amendment submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the July 22, 2009 Official Action. Accordingly, the initial response period is due to expire October 22, 2009. This amendment and request for reconsideration is being filed before the expiration of the initial response period.

As another preliminary matter, the requirement for restriction set forth in the February 26, 2009 Official Action has been made final, and subject matter not embraced by Group VI and claims 3-13, 18-24 and 27-34 has been withdrawn from further consideration in this application as being directed to non-elected inventions. Applicants reiterate that the election made in response to the aforementioned restriction requirement was without prejudice to their right to file one or more divisional applications, as provided in 35 USC §121, directed to any subject matter held finally withdrawn from consideration herein.

Turning to the substantive aspects of the July 22, 2009 Official Action, claims 2, 14-17, 25, 26 and 35-37 stand rejected for allegedly failing to comply with the enablement provision of 35 USC §112, first paragraph. In this connection, the examiner states that the present specification, while being enabling for a composition for the treatment of breast and prostate cancer, does not reasonably provide enablement for a composition for treating all cancers and all chronic viral infections.

Claims 2, 14, 15, 25, 26 and 35-37 have also been provisionally rejected for alleged obviousness-type double patenting, based on claims 11 and 12 of co-pending U.S. Application No. 12/418,173.

The foregoing rejections constitute all of the grounds set forth in the July 22, 2009 Official Action for refusing the present application.

In the July 22 Official Action, the examiner also states that claim 1 would appear allowable over the prior art of record, provided it is amended so as to be directed solely to the subject matter of elected Group VI.

In accordance with the present amendment, claim 1 has been amended such that it is directed solely to the Group VI subject matter which was elected in response to the aforementioned restriction requirement.

The claims withdrawn from consideration in the July 22 Official Action have been cancelled in accordance with this amendment, along with claims 25 and 26. The cancellation of the last-mentioned (non-withdrawn) claims should not be construed as indicative of applicants' concurrence or acquiescence in any rejection thereof set forth in the July 22 Official Action, or otherwise as an abandonment of applicants' efforts to secure patent protection on the subject matter recited therein. On the contrary, these claims are cancelled without prejudice to applicants' right to file and prosecute one or more continuing applications directed to the subject matter of the cancelled claims, as provided under 35 USC §120.

Regarding the rejection of claims 2, 14-17 and 35-37 based on 35 USC §112, first paragraph, applicants respectfully take exception to the examiner's position that the scope of enablement provided by the present specification is not commensurate with the scope of protection sought by the rejected claims.

This is not a case in which applicants are attempting to characterize the pharmaceutical compositions of claims 2, 14-17 and 35-37 by their respective uses. *Cf., In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). On the contrary, the pharmaceutical compositions embodying applicants' invention are claimed on the basis of their specific components, namely, an effective amount of an IDO inhibitor having the structure set forth in claims 2, 14-17 and 35-37, together with a pharmaceutically acceptable carrier medium. The claim language in question is merely a statement of intended use of the sort commonly recited in composition claims. It is well-established that a claim preamble that describes the use of an invention generally does not limit the claim because the patentability of composition claims depends on the claimed elements, not on the use or purpose of the elements. *Catalina Marketing Intl. v. Coolsavings.com, Inc.*, 62 USPQ2d 1781, 1785. The court in *Catalina* further stated in this regard:

[T]his means that a patent grants the right to exclude others from making, using, selling, offering to sell or importing the claimed apparatus or composition for any use that apparatus or composition whether or not the patentee envisions such use. Again, statements of intended use or asserted benefits in the preamble may, in rare

instances, limit [applicant's] claims, but only if the applicant clearly and unmistakably relied on those uses or benefits to distinguish prior art. [Id.]

In the present case, applicants are not relying on the statement of intended use in the preambles of claims 2, 14-17 and 35-37 to distinguish the claimed compositions over prior art.

Given the present circumstances, the statements of intended use in the preambles of claims 2, 14-17 and 35-37 do not limit the scope of the claims because such statements merely refer to the context in which the invention operates. *Boehringer Ingelheim Vet Medica v. Schering-Plough Corp.*, 65 USPQ2d 1961, 1965 (Fed. Cir. 2003).

In summary, the preambles of claims 2, 14-17 and 35-37 do not serve to limit the claims' scope. Indeed, the statement of intended use in each of these claims is not in any way a patentable limitation. Accordingly, the preambles of claims 2, 14-17 and 35-37 cannot properly be taken into account in determining whether or not claims 2, 14-17 and 35-37 comply with the enablement requirement of 35 USC §112. Nevertheless, in the interest of advancing prosecution of this application, and without acquiescing in the propriety of the present rejection, claims 2, 14-17 and 35-37 have been amended to delete the recitation that gave rise to this rejection. Support for the foregoing amendment of the composition claims is provided in the present specification at page 13, lines 1-2, page 15, lines 18-34 and page 20, lines 26-29.

As for the obviousness-type double patenting rejection of claims 2, 14, 15 and 35-37, based on certain claims of U.S. Application No. 12/418,173, it is hereby requested that this rejection be held in abeyance or deferred, until such time as it is the only rejection remaining in this application. In that event, the rejection should be withdrawn so that either the present application or the '173 application may be passed to issue, with the provisional double patenting rejection being converted to a non-provisional double patenting rejection in the other application, as authorized by §804 of the Manual of Patent Examining Procedure.

In view of the present claim amendment and the foregoing remarks, all of the claims now pending in this application are believed to be in condition for allowance. Accordingly, the issuance of a Notice of Allowance is believed to be in order, and such action is earnestly solicited.

Respectfully submitted,

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